

1 RECORD OF ORAL HEARING

2  
3 UNITED STATES PATENT AND TRADEMARK OFFICE

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6 BEFORE THE BOARD OF PATENT APPEALS  
7 AND INTERFERENCES

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10 Ex parte DEBORAH A. SCHADE,  
11 KIMBERLY L. MERKEL, and  
12 JAMES W. HANSEN

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15 Appeal 2007-0861  
16 Application 09/381,484  
17 Technology Center 1600

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20 Oral Hearing Held: Wednesday, September 12, 2007

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24 Before ERIC GRIMES, LORA M. GREEN, and RICHARD M.  
25 LEBOVITZ, Administrative Patent Judges

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28 ON BEHALF OF THE APPELLANTS:

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2 Application 09/381,484

1 The above-entitled matter came on for hearing on Wednesday,  
2 September 12, 2007, commencing at 1:00 p.m., at the U.S. Patent and  
3 Trademark Office, 600 Dulany Street, 9th Floor, Hearing Room A,  
4 Alexandria, Virginia, before Jan M. Jablonsky, Notary Public.

5 JUDGE GRIMES: Good afternoon, Mr. Jones.

6 MR. JONES: Good afternoon.

7 JUDGE GRIMES: As you may know, you will have 20  
8 minutes to present your argument once we get started. We do have a lot of  
9 cases to get through, so we're going to have to observe the time limit pretty  
10 closely.

11 MR. JONES: I'm sure I won't take 20 minutes.

12 JUDGE GRIMES: All right. Whenever you're ready.

13 MR. JONES: Thank you, Your Honors. If I may proceed?

14 JUDGE GRIMES: Certainly.

15 MR. JONES: If it please the court. There are two keys to keep  
16 in mind in considering the patentability of the invention that we are hearing  
17 about today. Those two keys, in my mind, are, number one, this is a method  
18 claim, a method invention, not a composition or product invention; and,  
19 secondly, it is a method administered to pre-term infants, not term infants.  
20 And I will talk about primarily those two issues today.

21 First of all, as I said, our inventors invented a method, the  
22 composition itself which is an infant formula containing DHA and ARA,  
23 and of course I'm using those for Docosahexaenoic acid and Arachidonic  
24 acid, because it's a lot easier to say. The composition itself, the  
25 supplementation of an infant formula with ARA and DHA was not --  
26 admittedly, the Kyle patent shows that in fact the product that my client sells

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1 actually uses the Kyle oil in its commercial product. There's no question  
2 that even in the amounts set forth in our claim, but what was not known at  
3 the time of this invention was that an ARA and DHA supplemented infant  
4 formula could be fed to an infant to result in an increase in weight gain.

5           And the increase in weight gain, the enhancement of the weight  
6 gain is particularly noticed if you'll look at our study, the study that's set  
7 forth in our examples in our specification. The weight gain that was present  
8 here actually allowed our pre-term infants to catch up with normal-term  
9 infants. It's not a comparison of pre-term infants to other pre-term infants.  
10 It's actually an enhanced weight gain that allows infants fed with this  
11 supplemental ARA and DHA formula to actually catch up to healthy  
12 normal-term, even breast-fed infants who may not be fed an infant formula,  
13 and that's the method that was developed by the inventors here. And we  
14 don't believe the Examiner has appreciated that fact. We saw in the  
15 Examiner's answer an indication that the Examiner was not giving patentable  
16 weight to the term "weight gain enhancement" or enhancement of, let's see, a  
17 method for enhancing the weight gain with the pre-term infants. That's an  
18 argument that we dealt with early on in prosecution, and it never rose its  
19 head again until the Examiner's answer in this appeal.

20           JUDGE GRIMES: Well, let's talk about that. I'm having a hard  
21 time seeing how that preamble limits the scope of the claim. If you had a  
22 method disclosed in the prior art where the same composition was given to  
23 pre-term infants for a different purpose, say for brain development, how  
24 would that differ from what you're claiming?

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1 MR. JONES: It differs because we actually incorporate the  
2 preamble into the limitations in the claim. I mean, we have a  
3 weight-gain-enhancing amount. I mean, this is a method.

4 JUDGE GRIMES: Right, but that's defined as being at least ten  
5 milligrams of ARA and at least 30 milligrams of DHA. So that's your  
6 weight-gain-enhancing amount. If you had a method that disclosed  
7 administering, feeding, that same amount, even though it wasn't called  
8 weight-enhancing, how would that differ from what your claiming?

9 MR. JONES: Well, the difference is this is a method claim. I  
10 mean, in the preamble in a method claim, unlike, sometimes, the preamble in  
11 a product claim or a composition claim, actually does give life and meaning  
12 to the claim. I mean, it would be as if, let's say, somebody invented a  
13 method for administering orange juice to a patient to treat cancer. I mean,  
14 obviously, people have ingested orange juice and they probably have cured  
15 cancer in certain cases.

16 But the method claim would be a method for curing cancer by  
17 administering orange juice and in certain amounts. And so that's the type of  
18 claim this is -- just a method claim -- where the treatment of cancer; or, in  
19 this case, the method of enhancing weight gain, is actually what is patented.  
20 The aspect of feeding DHA and ARA to an infant is not patentable, because  
21 that is in the prior art. But it's the method of using the DHA- and  
22 ARA-supplemented infant formula for the purpose of increasing weight  
23 gain.

24 JUDGE GRIMES: You see, I don't think I agree with your  
25 analysis; your hypothetical. If you had a method of treating cancer by  
26 administering orange juice and there was prior art teaching cancer patients

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1 drinking orange juice in the same amounts, I think that would be  
2 unpatentable, because that method had been practiced, and there's no active  
3 difference that the purpose for which it's being carried out doesn't change  
4 how the method steps were actually practiced.

5 MR. JONES: Well, Your Honor, I respectfully disagree with  
6 that.

7 JUDGE GRIMES: Well, how would it differ? If I'm drinking  
8 orange juice and I'm thinking I'm going to cure my cold, but it turns out I  
9 have cancer and it cures my cancer, does what's going on in my head when  
10 I'm doing the same thing -- change the method?

11 MR. JONES: Well, what you're talking about, I assume, is an  
12 inherent property.

13 JUDGE GRIMES: Yes. I think it comes down to inherency.  
14 Yes.

15 MR. JONES: You're talking about an inherent property that  
16 someone ingesting orange juice would have inherently cured cancer. Well,  
17 Your Honor, quite frankly, that's the case with every old method claim with  
18 every -- I should say old method claim. That's the case with every old  
19 composition that is applied in a new method. I mean, it's always fed -- if  
20 you look at this infant formula art, if you go in Class 426, and I believe the  
21 sub -- the primary sub in infant formula is 801. If you go there, you will see  
22 lots of claims that have been allowed over the years where the product has  
23 actually been fed to infants. I mean, this is all infant formula. It's been fed  
24 to infants. It's been fed to pre-term infants. It's been fed to breast-fed  
25 infants who go off of breast-feeding and then start ingesting infant formula.

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1 There are lots of claims that have been allowed that are very similar to this  
2 claim that we are hearing about today.

3 JUDGE LEBOVITZ: But what about with Crozier? Crozier  
4 teaches administering both these compounds to pre-term infants.

5 MR. JONES: Yes, sir, it does.

6 JUDGE LEBOVITZ: So, pre-term infants have ingested ARA  
7 and DHA. Now, the reason for it may be different, but inherently, they  
8 gained weight and in fact all the steps of the method claim -- the claimed  
9 method claim -- were carried out in the prior art. The only difference is no  
10 one recognized, at least explicitly, that in addition to helping brain  
11 development, they also gained weight.

12 MR. JONES: Well, in addition, Crozier says one other thing.  
13 Crozier says that when DHA only was administered to infants, then you had  
14 a weight-gain depression, they actually did not gain weight. There's actually  
15 a teaching away in the confines of Crozier itself, which says when DHA is  
16 added -- when DHA from fish oil is used in infant formula -- the studies  
17 show that there was actually a decrease in weight gain. It says weight gain  
18 was depressed.

19 JUDGE GRIMES: But doesn't Crozier then attribute that to the  
20 Eicosa-Pentanoic acid that was also present in the fish oil that was used?

21 MR. JONES: Crozier does do that.

22 JUDGE GRIMES: And then it goes on to advise administering  
23 DHA, but using a different source.

24 MR. JONES: Yes, it does. But then it does cite to the Carlson  
25 study. If you go to the 1996 Carlson study, which I believe is in the record,

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1 you will see that it is a direct teaching that DHA-administered formula  
2 decreases.

3 JUDGE LEBOVITZ: But isn't the only issue here -- well, it  
4 would have been obvious to administer both of them, both DHA and ARA;  
5 and what about Kyle, who actually teaches administering both of those?

6 MR. JONES: That's correct. Yes, Your Honor, Kyle does  
7 teach, as I said earlier. Kyle teaches it in the concept, however, of infants in  
8 general. No teaching of administered to pre-term infants, and that's where  
9 the necessity for the limitation on the pre-term infants comes into play.

10 Now, one of the things that we thought about doing during  
11 prosecution was adding a limitation to the claim about what we call the  
12 catch-up -- not k-e-t-c-h, but the c-a-t-c-h, the catch-up -- to normal infants.  
13 We argued that, but we never put that into our claim because we didn't  
14 believe that the art as cited led you to this invention without that aspect.  
15 Now, whether that's patentable or not, we certainly believe it's also  
16 patentable. But I know that's not part of the claim here today. We just  
17 decided not to put that limitation in.

18 JUDGE GRIMES: I'd like to move to your unexpected results  
19 argument, if we could.

20 MR. JONES: Yes.

21 JUDGE GRIMES: You say in your brief that you think that  
22 Crozier is the closest prior art. It seems to me that Kyle's teaching of an  
23 infant formula that actually contains these two compounds in amounts that  
24 are pretty close to what's in your claims, it seems to me that that's the closest  
25 prior art that should be the basis of a comparison.

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1 MR. JONES: Well, we believed Crozier was because -- again,  
2 this is a method patent. This is a method claim, and the method of Crozier is  
3 feeding to pre-term infants. That's the second important point I wanted to  
4 make is that we're not talking about being fed to term infants. We're talking  
5 about being fed to pre-term infants, and then the unexpected result is the  
6 catch-up that I just talked about.

7 JUDGE LEBOVITZ: So, you're saying that when you  
8 determine what's the closest prior art, it's not the composition, but it's the  
9 method claim. And in this case, the closest prior art would be the method of  
10 Crozier.

11 MR. JONES: That's what we believe, Your Honor, because  
12 Crozier actually indicates DHA and ARA being fed to pre-term infants. And  
13 so, I mean I know the Examiner cited Kyle as the main reference, and I  
14 guess that's because Kyle is the composition, but again, it's not a  
15 composition claim. It's a method claim.

16 JUDGE GRIMES: But if Crozier's disclosure of feeding DHA  
17 and ARA to pre-term infants is the closest prior art, then I don't see that  
18 comparison in your spec. Your comparison is with DHA alone or nothing to  
19 DHA and ARA at these levels. Right?

20 I mean, if Crozier's teaching of administering DHA and ARA to  
21 pre-term infants is the closest prior art, then wouldn't the unexpected results  
22 have to be from the amount that you're feeding? Because that's the only  
23 difference in this claim as compared to your characterization of Crozier.

24 MR. JONES: Well, no, Your Honor. We don't believe that to  
25 be the case because the unexpected result is the weight enhancement in  
26 pre-term infants. And Crozier, we believe studies as cited in Carlson, or by



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1 citing Carlson -- and talking about Carlson's study, actually says if you feed  
2 DHA to an infant, you will see a weight-gain depression. Now, Crozier  
3 made no statement at all about weight-gain enhancement. Crozier, we  
4 believe, does not say anything about weight gain, except that it does say that  
5 coupled with Carlson, that fed DHA or feeding of DHA will depress weight  
6 gain.

7                   And so, the comparison -- the unexpected result is really the  
8 unexpected result versus something that taught away from the result reached,  
9 which was an enhancement of weight gain to allow catch-up to a  
10 normal-term infant. And, I mean, I know I've had enough appearances in  
11 Europe that oftentimes Examiners there, and the Boards there make you start  
12 from the closest piece of prior art. I've never done that in the U.S. -- in a  
13 U.S. case -- because at least my understanding of the law in the U.S. is you  
14 don't really have to start from the closest piece of prior art. You look at all  
15 the prior art together and the question is whether or not that prior art taken  
16 together would make the invention obvious.

17                   JUDGE GRIMES: Well that's true, but if you're relying on  
18 unexpected results to overcome a prima facie case of obviousness, then you  
19 have to compare it to the closest prior art.

20                   MR. JONES: Well, and we think we did that. I mean, the  
21 comparison was to infants that were fed with normal infants. And our study  
22 was on pre-term -- what was using obviously pre-term infants, because that's  
23 what our method is directed to -- just the feeding of this formula to pre-term  
24 infants.

25                   I mean, what we see as the differences are the method versus  
26 the composition claim, and that's why the preamble does make a difference

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1 here and the weight enhancement -- or the weight-gain enhancement -- and,  
2 secondly, is the term versus pre-term infant category. We're not talking  
3 about being fed to term infants, like we assumed Kyle does.

4 Kyle doesn't mention pre-term infants at all. And like I say, we  
5 considered putting in a limitation comparing it to the catch-up and catching  
6 up within a certain number of months, or et cetera, whatever our study  
7 shows. But just don't believe at this point that we have to do that because  
8 we believe it's patentable over the prior art that's cited.

9 Thank you.

10 JUDGE GRIMES: Any other questions?

11 JUDGE LEBOVITZ: No.

12 JUDGE GRIMES: Thank you.

13 (Whereupon, at 1:20 p.m., the hearing was concluded.)  
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